

# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH



Raul Pino, M.D., M.P.H.  
Commissioner

Dannel P. Malloy  
Governor  
Nancy Wyman  
Lt. Governor

### Healthcare Quality And Safety Branch

October 12, 2018

Vincent Capece, Jr., Administrator  
Middlesex Hospital  
28 Crescent Street  
Middletown, CT 06457

Dear Mr. Capece, Jr.:

An unannounced visit was made to Middlesex Hospital on September 17, 2018 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting an investigation.

Attached is a violation of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which was noted during the course of the visit.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

**The plan of correction is to be submitted to the Department by October 26, 2018.**

The plan of correction shall include:

- (1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;
- (2) the date each such corrective measure or change by the institution is effective;
- (3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and
- (4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violation and you may be provided with the opportunity to be heard. If the violation is not responded to by October 26, 2018 or if a request for a meeting is not made by the stipulated date, the violation shall be deemed admitted.

We do not anticipate making any practitioner referrals at this time.



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DATE OF VISIT: September 17, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT  
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES  
WERE IDENTIFIED

If there are any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Cheryl Davis, R.N., B.S.N.  
Supervising Nurse Consultant  
Facility Licensing and Investigations Section

CAD:lst

CT #23764

DATE OF VISIT: September 17, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT  
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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1) and/or (2) and/or (3) and/or (4) and/or (i) General (6).

1. Based on a review of hospital documentation, hospital committee meeting minutes, e-mail communications, interviews and policies, the hospital failed to regain a state of control in the Clean Room, where sterile products are compounded, after a small water leak was identified. Subsequent to the water leak and before proper sanitation of the room, staff compounded 37 medications that were administered to twenty (20) patients. The finding includes:
  - a. Review of facility documentation dated 7/23/18 identified that during a heavy rainstorm on 7/17/18, water penetrated the exhaust system of the biological safety cabinet (BSC) located in the pharmacy Clean Room which is utilized to compound chemotherapy. Facility documentation noted that 37 medications were compounded using the LAFW, located in the same room as the BSC during the period of 7/17/18 at 11:00 PM through 7:00 AM on 7/18/18 and administered to Patient #1-20 on 7/18/17.

Interview with Pharmacy Technician (PT) #1 on 9/17/18 at 11:10 AM indicated that on 7/17/18 at approximately 8:00 PM she observed a small amount of water on the floor of the Clean Room in front of the entry door next to the BSC. PT #1 stated she wiped up the water and notified the charge pharmacist (Pharmacist #1). PT #1 stated that the Pharmacist told her she should clean the room like she normally does, since this was not a good thing and should take major steps to clean. PT #1 stated she cleaned the room utilizing bleach, alcohol, Cavicide wipes, and alcohol again. Review of the cleaning log dated 7/17/18 failed to identify that PT#1 cleaned the room. The cleaning log reflected that a three time clean was completed on 7/18/18 by another pharmacy technician.

Interview with Pharmacist #1 on 9/17/18 at 8:50 AM indicated that when she was notified of the issue on the evening of 7/17/18 by PT #1, she asked PT #1 to check for further leaks and when informed that there were none, asked PT #1 to clean the room as she normally does. Pharmacist #1 indicated that the other pharmacist on duty (Pharmacist #2) texted the Operations Director to notify him of the issue at that time.

Interview with the Operations Director on 9/17/18 at 11:30 AM indicated that he was notified of the water leak on 7/17/18, however, he misunderstood the text and assumed the water leak was in the "new clean room" that was under construction and had been leaking earlier in the day.

Interview with the Director of the Pharmacy on 9/17/18 at 8:50 AM and 12:15 PM respectively stated she was notified in the morning of 7/18/18 that PT #1 observed water on the BSC and on the floor beneath the cabinet (on 7/17/18) and notified the charge pharmacist. The Director stated the area was cleaned, however, she was not notified of the incident and compounding was not suspended until she was notified in the morning.

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The Director stated she was informed that a three-time clean was completed by PT#1 on 7/17/18 but during her discussion with PT#1, the Technician revealed that the products utilized to disinfect the cleanroom after the water leak failed to include a sporicidal. The Director identified she directed only low risk medications be compounded with a one-hour beyond use date (BUD) effective 7/18/18.

Review of facility documentation identified that weekly environmental samples of the clean room were obtained during the period of 11/17 through 9/17/18 and revealed no growth.

Review of the policy entitled, Sanitation of the Controlled Sterile Compounding Environment, stated that the LAFW and BSC are most intimate to the exposure of critical sites and require disinfection most frequently. Three-time cleaning of controlled environments include the use of two germicidals (alcohol and Cavicide), and a sporicidal (Peridox) and may be performed when the following conditions occur, in part; first use and testing of a new facility, after maintenance work, after action levels are identified, and/or at the discretion of the Pharmacy Manager. The policy directed that the cleaning must be documented.